BD

MASSACHUSETTS - PRESCRIPTION ABUSE DATA SYNTHESIS

INTERIM REPORT

MARCH 1984

DEPARTMENT OF PUBLIC HEALTH
DIVISION OF FOOD AND DRUGS

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PADS (Prescription Abuse Data Synthesis) -INTERIM REPORT

I. INTRODUCTION

A. The drug problem in Massachusetts as in other states is by no means restricted to illegal drugs. The problem in the Commonwealth includes the diversion and abuse of legal prescription drugs. The causes for this growing problem include practitioners who misprescribe, pharmacists who purposely divert drugs, thefts and forgeries of prescription forms and thefts of drugs from legitimate sources, mainly pharmacies.

Practitioners who misprescribe can be placed in four categories:

1) "Dishonest" physicians who consciously misprescribe drugs for drug abuse purposes, for profit, or for sexual favors;

2) "Duped" physicians who unwittingly acquiesce to insistent demands by patients for medication;

3) "Dated" physicians who have not kept themselves current with developments in pharmacology;

4) "Disabled" physicians who are themselves drug abusers or drug dependent.

A plan to help states reduce prescription drug abuse and diversion is being field tested by the American Medical Association in five states. Massachusetts was selected to participate in the field test.

B. PADS (Prescription Abuse Data Synthesis) is designed to assist state authorities in defining the nature, magnitude, locus and source of prescription drug diversion within their state. It uses a coordinated effort between state agencies and professional associations to use existing data systems to identify the diversion problem and inventory the state's ability to intervene.

The use of multiple sources of information is the basis of the PADS model. When more than one source of information is used to identify drug diversion there is a greater probability that the problems identified will be accurate. Information sources are divided into both supply-side and demand-side.

The problem-solving approach recommended by PADS integrates several information systems in order to focus on the accurate sources of drug diversion. Once these sources of diversion have been identified, the next step in the PADS process involves the formulation of intervention strategies that address the diversion problem.

The method for developing a strong PADS model in a state demands the cooperation of more than one state agency or professional organization. Since no single state agency has the authority or

capability to deal with the diversion problem, PADS recommends that a comprehensive interdisciplinary approach be taken. This would then include representatives of the health care professions, licensing boards, regulatory agencies, law enforcement authorities and regional federal agencies.

C. In Massachusetts there has been continued interest in reducing prescription drug abuse by state regulatory agencies, the legislature, law enforcement authorities, health care organizations and the media. In late Spring of 1982 strong legislative and Department of Public Health support developed for a program which would monitor the use of prescription drugs. Extensive media coverage exemplified specific details on the abuse of prescription drugs, mainly by physicians who illegally and inappropriately prescribe drugs which have a high potential for abuse.

In 1982, a bill was introduced to the legislature which would require the establishment of a prescription monitoring program through the use of a multiple copy prescription form. An initial appropriation was given to the Department of Public Health for Fy'83 for the first stage of program development. Soon after, the Department convened a Controlled Substances Advisory Board which was widely representative of physicians, pharmacists and law enforcement authorities. Individual task forces convened to determine the type of monitoring system to advocate. By the end of 1982 it was decided by the Department, based upon the recommendation by the Advisory Board, that a duplicate copy prescription monitoring program for schedule II drugs be implemented. Additional funding was requested to establish such a monitoring system. This was to be offset, however, by proposed revenue from an annual registration fee of the 20,000 plus practitioners registered to prescribe controlled substances. Currently, practitioners pay a one-time only fee. The final budget for Fy'84 deleted all funding for a prescription monitoring program. At this point all substantive planning for a prescription monitoring program have ceased. In the event such a program is implemented PADS can enhance the sharing of information.

D. Massachusetts is one of five states where PADS has been field tested. The others are: Florida, Nevada, Michigan and Arkansas.

Massachusetts involvement with PADS began in October 1983. Both policy and technical groups were formed. The sponsoring organization, is the Department of Public Health, Division of Food and Drugs,and has been responsible for initiating project activities, providing support staff, and serves as a single point of communication for both the AMA and its technical Consultants, Applied Resources Corporation. The PADS model tries to involve a sponsoring organization whose role in the diversion problem includes all the prescription and dispensing professions. The Massachusetts Department of Public Health, Division of Food and Drugs is a regulatory agency and is entrusted with registering all persons who distribute, dispense, prescribe, conduct research, or otherwise

handle controlled substances. The policy group is the coordinating body for the project. It includes representatives of the Massachusetts Medical Society, the State Boards of Registration in Medicine, Pharmacy, Dentistry and Nursing, the State Police, Attorney General's Office, the Regional Office of the Drug Enforcement Administration, the Department of Public Health's Division of Drug Rehabilitation and the Massachusetts Hospital Association. The technical group provides the expertise on the data systems used in the PADS model. It includes representatives of some of the above mentioned groups, and individuals who specifically have knowledge of the information systems.

To date, two technical and three policy meetings have taken place. (See attached list of meeting dates, attendees and invitees not in attendance). Preliminary data has been gathered and the remainder of this report will summarize that data and discuss the next step for PADS in Massachusetts.

II. PROBLEM IDENTIFICATION

A. ARCOS - (Automation of Reports and Consolidated Orders System) - The ARCOS system monitors the flow of selected drugs from point of import or manufacture to the point of sale, export or other distribution. the system provides for the audit of drug inventory transactions for the controlled substances as declared by the Federal Controlled Substances Act (Schedule II, III-narcotic). Included are compounded drugs containing ARCOS reportable drugs.

A subsystem of ARCOS, The Diversion Analysis and Detection System (DADS) reflects direct sales made from the wholesale level to the retail level. The retail level consists of retail pharmacies, hospitals/clinics, physicians and teaching institutions. It enables the DEA to measure the extent to which the controlled substances are distributed into any area of the country and helps them identify the recipients of the substances.

1) Exhibit A- illustrates the per capita distribution of the major ARCOS reportable drugs.

2) Exhibit B- the Commonwealth of Massachusetts ranks second in the nation in the per capita distribution of oxycodone. This chart trends oxycodone distribution in Massachusetts over a four year period.

B. DAWN - (Drug Abuse Warning Network) - this large scale drug abuse data collection system jointly sponsored by the DEA and NIDA is designed to :

1. identify substances associated with drug abuse episodes.

2. monitor drug abuse patterns and trends and to detect new abuse entities and combinations.

3. assess the health hazards associated with drug abuse.

4. provide data for national, state and local drug abuse policy and program planning.

The DAWN system collects reports of drug related hospital emergency room visits and deaths from approximately 900 facilities, including emergency rooms and medical examiners in 26 Standard Metropolitan Statistical Areas (SMSA's). DAWN facilities report all episodes of drug related visits to emergency rooms and drug related deaths encountered by medical examiners. Massachusetts has 33 emergency rooms which participate in the DAWN system. Each report of a drug episode include demographic information about the patient or deceased, as well as information about the circumstances of drug use. NIDA uses DAWN as a mass screening device to give an early indication of changing drug use patterns and is able to detect small, slow changes in use patterns that might be overlooked in quarterly and annual compilations. DAWN provides the most systematic and consistent national reporting of morbidity and mortality associated with drug use.

There are several limitations to DAWN data. In no case is there complete coverage of a state. Demographically, rural populations are under represented. Only a small percentage of emergency room overdoses use similar drug identification procedures. Emergency room personnel rely on self-reporting of drugs taken and there is reason to question the complete accuracy of such reports. From this data, it cannot be assumed that there has been consistent abuse of drugs as a result of a single death or overdose report.

1) Exhibit C-1982 DAWN Data: Boston/National

In order to determine if the high supply of oxycodone involves diversion we look at data from the Drug Abuse Warning Network (DAWN). In 1982, 2.6 percent of the emergency room mentions in Boston involved oxycodone. This compared to 1.6 percent in the nation as a whole.

2) Exhibit D-1982 DAWN Data: Boston/National

DAWN data showed a possible problem with tranquilizers. We first graphed Schedule IV drugs as a group which constitute 23.7 percent of the episodes in Boston versus 16.7 percent in the nation as a whole.

3) Exhibit E-1982 DAWN Data: Boston/National
Graph V - 1982 DAWN Data: Boston/National

In this graph we looked at diazepam, the most frequently mentioned tranquilizer in the DAWN Data. 17.3 percent of the emergency room mentions in Boston involved diazepam versus 16.7 percent in the nation as a whole.

C. Massachusetts Laboratory Analysis - This information has been compiled from the records of the State Laboratory Institute, Drug Analysis Laboratory, 305 South Street, Jamaica Plain, Massachusetts.

The drugs represent cases submitted by law enforcement agencies, mostly city and town police departments, from all of Massachusetts, east of Worcester, including Cape Cod and the Islands.

Submission refers to one sample analysis card. A case with one defendant may contain one submission or many submissions. One submission may refer to one tablet or capsule or may refer to thousands of tablets or capsules.

Example:

Defendant found with 3 diazepam tablets in a manila envelope. Three tablets in one manila envelope = 1 submission.

Defendant found with 20 flurazepam capsules in a plastic bag and four bottles of methaqualone tablets at 1000 tabs per bottle. 20 flurazepam capsules in plastic bag = 1 submission, 4 bottles with 1000 methaqualone each = 1 submission.

1) Exhibit F-Massachusetts Lab Submissions

Another indicator system used in the PADS process involves the laboratory analysis of drugs seized during arrests. Of 667 submissions of prescription drugs during a statistical sampling process, 430 involved commonly abused drugs. Diazepam accounted for 35 percent of these submissions, oxycodone for 14 percent.

D. CODAP - (Client Oriented Data Acquisition Process) - is a required reporting process for all drug abuse treatment and rehabilitation units that receive federal funds. It's data reflects all clients treated at reporting facilities regardless of funding support for any particular client. Client characteristics reported through CODAP include age, sex, race, marital and employment status, number of times arrested within 24 months of admission, primary drug of abuse at admission, frequency of use of primary drug, route of administration, secondary and testing drugs of abuse at admission, and other relevant information.

CODAP drug categories do not always separate prescription drugs from similar non-prescription drugs. Since CODAP does measure the effects of drug abuse it can be used to evaluate the relative impact of prescription drug abuse as compared with abuse of illicit drugs such as heroin and marijuana. This information can be used in a year-to-year trend analyses to monitor changing levels of prescription drug abuse, and to evaluate the effects of efforts to reduce prescription drug diversion and abuse.

1) Exhibit G-CODAP Data
Comparison between Massachusetts and the nation

2) Exhibit H

Another indicator of potential diversion involves admissions to drug treatment programs. The Client Oriented Data Acquisition Process (CODAP), the national system for reporting such admissions ended in 1981. Individual states still collect this data in some form, but 1981 is the last year in which we can compare particular states with the nation as a whole. By doing so, we see that the other opiate category, the second box from the bottom involved 11 percent of the treatment admissions in Massachusetts while only 8.2 percent in the nation as a whole. While we were looking at the other opiate category, which includes such drugs as oxycodone, we noticed that the Massachusetts admissions for tranquilizers was 5.6 percent versus 2.5 percent for the nation as a whole. This is shown at the box at the bottom of the graph. We decided to look into this further.

E. Statistics on Criminal Justice System Activity

The Department of Public Health's drug laboratory analyzes drugs submitted by local police departments. This data illustrates the kinds of drugs seized on the street, as well as the number of arrests.

The State Police drug laboratory services the state police activities. We requested data from this laboratory but realized there is no systematic data gathering system.

The Diversion Investigative Unit of the Massachusetts State Police compiles statistics on the number of arrests, complaints, voluntary surrenders, audits, armed robberies of phamacies and violations of controlled substance laws by practitioners.

III. Gaps in Information Systems

A. MMIS- (Medicaid Management Information System) - is a computerized system which provides the capability to monitor reimbursements for all Medicaid services, including prescribed drugs through a process

called Drug Utilization Review. Approved providers routinely submit claim forms which identify the recipients, prescribers and dispensers of controlled substances, as well as the amount of product dispensed and dates of service. This system has the capability to detect provider abuses and prescription shoppers. Because MMIS information identifies recipients, it is available only to state law enforcement and regulatory agencies.

Several factors create limitations with the MMIS data because the information received is only as a result of drug purchases by Medicaid recipients. Therefore, data is available for a limited group of persons as defined by economic status . The Massachusetts MMIS is only in its implementation phase. Time frames for full implementation of the MMIS has not been projected. However, some information on prior claims can be retrieved. There is a Drug Usage File which is a report on recipients and which lists the drugs which are paid for by the State. When abuse by a recipient is detected the Department assigns that recipient to a particular pharmacy where they will be required to make their purchases.

Some of the PADS states have used MMIS data to develop practitioner/provider targetting lists. The reports are generated at a second or third standard deviation level indicating that these providers are writing an unusually high number of controlled substance prescriptions. Massachusetts MMIS is not currently producing such a report. Since MMIS is client specific, the detection process is a helpful but limited constructive tool. However, MMIS can be used to detect diversion problems such as doctor shopping.

B. Prescription Monitoring - Earlier in this report we used examples of existing data systems used in identifying diversion. Each of these systems has severe limitations. ARCOS only reports schedule II & III-narcotic drugs, and identifies only the purchaser of the drug not the prescriber. DAWN, CODAP, and Laboratory Analysis Data measure the impact on diversion on public health and criminal justice activity, but also does not identify the prescriber. Even if MMIS were fully functioning it would only cover Medicaid recipients. In response to these data system limitations different states have taken varied program approaches. After careful study States such as Rhode Island, New York, California, Texas, and Hawaii opted for multiple prescription systems for schedule II drugs; Florida developed an approach which uses hand held computers to enter data by investigators; Wisconsin, New Hampshire, and Michigan opted for a consolidated system which utilizes already existing information systems. Multiple copy prescriptions create an investigative tool for use by the appropriate law enforcement agencies and the respective professional organizations. It is designed to target necessary investigative diversion activities. The final objective of such a system is to generate computer printouts which would provide data on each practitioner giving the name, quantity, and strength of schedule II drugs he/she has prescribed in a given time frame.

Whichever path is chosen it is essential that a cooperative effort be maintained in order for any program to operate efficiently and objectively. The participation of several state agencies as well as professional organizations is imperative.

IV. Diversion Intervention

A. Intervention - Thus far this report has been discussing how to identify diversion. Once diversion is identified actions to stop it are called intervention. Historically, the Diversion Investigative Unit of the Massachusetts State Police and the regulatory boards have shared information. Cooperative inter-agency efforts rarely, if ever, have been conducted, and intervention through professional associations has never been utilized. After specific sources of diversion have been identified and classified, it is essential that an intervention strategy be formulated that is responsive to the precise nature of the problem. Interventions must be designed to have a reasonable chance of success in eliminating the diversion activity, without excessive or inappropriate force. A comprehensive approach must be initiated and followed through. Comprehensive meaning that there is a combined federal, state, and local response with strong involvement from professional as well as regulatory entities and that, in addition to law enforcement, strong educational and treatment programs be instituted.

Intervention includes professional educational programs for the duped and dated practitioner.

For example: 45% of the diversion problem stems from prescription forgeries; 45% is indiscriminate prescribing; 10% are from pharmacy armed robberies.

Although these are national figures, they are reflective in Massachusetts.

Therefore, education programs targetted toward prescription writing and pharmacists dispensing can be useful intervention tools. Impaired professional programs that provide carefully monitored treatment for practitioners whose diversion activities include self-use can also reduce diversion.

To date there is not a statewide comprehensive program in existence which is directed at reducing the prescription drug abuse problem in Massachusetts. From an overview all drug cases are being handled at the criminal level. This method of controlling diversion is very lengthy and costly. During the legal process, a diverter continues to practice medicine with little or no recourse. Cases sometime take years before they are finalized, and then there are appeals. In a vast majority of the cases the course of action is determined by a local District Attorney. If Board actions or Division of Food and Drug action can be taken in the interim it would serve as an adjunct to the judicial system and at least stop the prescriber from continuing that activity for which he/she is being prosecuted. The

ideal situation would be to remove the controlled substance registration and go criminally thus handling the situation more efficiently. It is understood that any administrative attempt at revocation or suspension could influence the decision at the criminal level. A concerted effort in separating the two, needs to be defined.

The participants in Massachusetts' discussion believe that this is possible but efforts to accomplish this goal have been hampered through bureaucratic rules, reorganizations, a change in political climate, confidentility requirements, and lack of communication.

On December 14, 1983 the Division of Food and Drugs mailed a letter (Exhibit I) to the following agencies: The Division of Drug Rehabilitation (Department of Public Health), the State Drug Laboratory, the Massachusetts Medical Society, the Department of Public Welfare, the Massachusetts State Police, the Board of Registration in Pharmacy.

Exhibit J includes the sum total of three responses to that letter, the Board of Pharmacy, the Massachusetts Medical Society, and the Massachusetts Nurses Association.

B. Model Intervention Formula - Intervention formulas used by many states involve criminal, administrative, educational and treatment resources. Decisions as to how to proceed with a case include criminal vs. administrative sanctions, and voluntary compliance for alleged violations. A single point of authority and responsibility can facilitate this decision-making process.

C. Professional Associations - Through its co-sponsorship of the PADS project, the Massachusetts Medical Society has shown its concern for the diversion problem as well as the lack of recognition of the problem by practitioners, their peers and consumers alike.

Some consumer recognition was generated two years ago but the impetus has somewhat died. Many professional societies and associations throughout the country offer impaired practitioner programs, and continuing education courses for potential problem practitioners. Massachusetts is one state which is still in its developmental phase in this area.

We still agree that there is substantial difference of opinion as to what constitutes "abusive" or "illegal" prescribing. There are no set guidelines which limit legitimate drug therapy for pain or psychiatric illness. These are variables which depend tremendously upon the patient and routine physician practices. Each case must be judged individually and according to prevailing standards of medical practice.

We had hoped for a similar level of committment from the Massachusetts State Pharmaceutical Association which has yet to develop its input.

V. Inventory of Intervention Capability

A. Criminal - The decision to take criminal action is made by law enforcement authorities. There is some question of whether this decision should be made by professionals. The diverter must be identified in such a way as to properly classify their level of criminal activity in accordance with the 4 d's. For example, the courts generally don't want to prosecute a doctor for drug addiction.

1) Drug Enforcement Administration - does not have the resources nor mandate to investigate all controlled substance registrants. The Boston Regional Office is responsible for 6 states with a staffing level at 4 investigators.

2) State Police - Within the past year the Diversion Investigative Unit has increased its manpower to 12 agents. Within the past 9 months, the D.I.U. has made 38 arrests for forged prescriptions, 14 arrests for physicians, 3 for nurses, 1 for a hospital employee, 2 for pharmacy employees, and 5 for pharmacists all due to violations of the controlled substances laws. They have received 65 complaints, conducted 85 pharmacy audits, and investigated 2 armed robberies of pharmacies.

3) Attorney General - resources available to initiate litigation which results in criminal, and/or administrative sanctions; have resources to investigate Medicaid fraud. However, this office does not have diversion investigation resources unless it is Medicaid related.

4) District Attorney - resources available to initiate criminal prosecution at the state and local levels against practitioners involved with the diversion of prescription drugs.

B. Administrative - The various agencies which have regulatory authority through their licensing mechanisms are listed below. Each agency is required by law to hold hearings on a particular registrant. This due process allows for expert testimony to be presented by witness, investigators, police, inspectors, and qualified professionals.

1) The Department of Public Health, Division of Food and Drugs - is responsible for the initial licensing for all controlled substance prescribers. This Department has the administrative authority to revoke, suspend or restrict controlled substances privileges exclusive of Board action or criminal recourse.

2) Boards of Registration - The Executive Office of Consumer Affairs has recently pooled all Registration Boards into one category with the exception of the Board of Medicine. This reorganization allows any Board investigator to be reassigned to any complaint at any time. All Boards have the authority to suspend, revoke, restrict licenses without criminal convictions.

a) Medicine-Resources-1 attorney, 2 investigators. Responsible for licensing and discipline of physicians and osteopathic physicians. Operates autonomously from other Boards. Licenses approximately 20,000 practitioners. This year there are 20 drug-related cases awaiting hearings, 22 drug-related complaints have been received, and disciplinary action has been taken against 9 practitioners.

b) Pharmacy-Resources-3 agents. Responsible for controlled substance licensing of pharmacists, wholesale and retail pharmacies. There are 1350 pharmacies, and 7136 pharmacists registered in Massachusetts. There are 10 cases waiting Board action and 20 complaints filed outstanding, 15 licenses have been suspended or revoked in the past year.

c) Dental Examiners - has one investigator; there are 7 drug related complaints pending, 3 awaiting hearings and 2 licensure actions taken in the past year. There are approximately. 5,000 dental licenses issued.

d) Veterinary and Podiatry Medicine - These Boards utilize the pool of investigators. There are approx. 1,000 registrations issued.

e) Nursing Board - Resources - uses the pool of investigators. Responsible for licensing 70,066 RN's, 23,290 LPN's. Recent legislation allows nurse practitioners to write prescriptions. This will add approximately 1100 controlled substance registrations prescribing under the supervision of a physician. There have been 95 complaints, mostly drug related, filed with the Board over a nine month period.

f) Physician Assistants - Recent legislation has allowed physician assistants to issue written prescriptions. This will add approximately 400 controlled substance registrations. There is no disciplinary authority or formal licensing requirement for physician assistants. Their supervision is entrusted with their supervising physician which ultimately rests upon the Board of Medicine.

VI. Continued PADS Activities

A. With the production of this report we have finished the first part of the PADS process, the primary analysis of the nature and extent of the diversion problem, and the inventory of intervention capabilities. The Technical Group has completed its role of providing available data to the Policy Group. The next step in the PADS process is to develop strategy options to improve our responses to the diversion problem.

We recommend to the Policy Group the formation of professional association and enforcement groups to review strategy options and develop work plans.

B. Strategy options need to be developed. Each group needs to look at the report and decide where they could be most beneficial. Some specific strategies which need to be considered are:

1. identify current provision in laws, regulations, policies and procedures which may be utilized now;

2. identify which laws need changing or new laws established;

3. analyze the decision making process criminal vs. administrative; could Massachusetts deal with it more effectively?

4. ways to best share existing information;

5. develop community, and legislative support for effective intervention;

6. look at existing impaired practitioner programs;

7. identify professional education programs;

8. what immediate action can the group take?

9. what long term strategies should be considered?

10. Are more resources needed at the civil, criminal, regulatory, and law enforcement levels?

11. What are the arguments for and against prescription monitoring program? duplicate?

12. Are prescription monitoring programs cost effective?

13. How should the impaired practitioner programs be developed? How should they be referred?

14. What further restriction should be placed on schedule II drugs? III drugs?

15. Should a Controlled Substance Board be established by statute?

16. Would there be any changes in the administration process?

17. How might information be best shared?

C. Workplan - We suggest that the Policy Group develop concrete workplans for the two subgroups to accomplish the review of the stategy options.

The Policy Group should set a target date for the production of a final PADS report with updated information and strategy option recommendations.

Attachment 1:

Massachusetts Technical Group October 26, 1983

Participants	Organization
James Rooney	Department of Public Health Division of Drug Rehabilitation
Vic Gelineau	Department of Public Health Division of Drug Rehabilitation
Dorothy Wagg	Department of Public Welfare
Carolyn Keely	Department of Public Welfare
Lt. Bill Sutherland	Mass. State Police
Ed D'Angelis	Mass. State Police
Neil Foley	Mass. Medical Society
Lou Pacifico	Board of Registry in Pharmacy
Jack Crowley	Drug Enforcement Administration
Barry Rhodes	Odyssey Resources, Inc.
James McGrath	Department of Public Health Division of Food and Drugs
Vivian Friedman	Department of Public Health Division of Food and Drugs

Invitees not in Attendance

Organization
Mass. State Pharmaceutical Association
Board of Registration in Medicine

Massachusetts Policy Group October 27, 1983

Participants	Organization
Tom Salmon	Department of Public Health Director, Division of Drug Rehabilitation
Lt. Bill Sutherland	Mass. State Police
Carmen Picknally	Assistant Attorney General
Patty O'Day	Department of Public Welfare
Pat Canny	Department of Public Welfare
Jan Selwitz	Board of Dental Examiners
Charles Monahan	Board of Registration in Pharmacy
Jim Barrett	Board of Registration in Medicine
Tony Colangelo	Mass. Hospital Association
Barry Rhodes	Odyssey Resources, Inc.
Nancy Ridley	Director, Division of Food and Drugs Department of Public Health
James McGrath	Department of Public Health Division of Food and Drugs
Vivian Friedman	Department of Public Health Division of Food and Drugs

Invitees not in attendance

Mass. Medical Society
Mass. State Pharmaceutical Association
Drug Enforcement Administration

Massachusetts Technical Group December 1, 1983

Participants	Organization
Kevin McCarthy	Mass. State Drug Laboratory
James Rooney	Division of Drug Rehabilitation Department of Public Health
Vic Gelineau	Division of Drug Rehabilitation Department of Public Health
Bill Paieda	Drug Enforcement Administration
Neil Foley	Mass. Medical Society
Lou Pacifico	Board of Registration in Pharmacy
Dorothy Wagg	Department of Public Welfare
Lt. Bill Sutherland	Mass. State Police
Charles Monahan	Board of Registration in Pharmacy
Barry Rhodes	Odyssey Resources, Inc.
James McGrath	Division of Food and Drugs Department of Public Health
Vivian Friedman	Division of Food and Drugs Department of Public Health

Invitees not in Attendance

Organization
Board of Registration in Medicine

Massachusetts Policy Group November 30, 1983

Participant	Organization
Bill Paieda	Drug Enforcement Administration
Mary Regan	Mass. Nurses Association
Tony LaMonica	Board of Registration in Pharmacy
Patty O'Day	Department of Public Welfare
Carmen Picknally	Assistant Attorney General
Tom Salmon	Director, Division of Drug Rehabilitation Department of Public Health
James Barrett	Board of Registration in Medicine
Jan Selwitz	Board of Dental Examiners
Bud Maitland	Mass. Dental Society
Dr. Carl Rosow	Mass. Medical Society
Ron Dudley	Board of Registration in Pharmacy
Charles Monahan	Board of Registration in Pharmacy
Tony Colangelo	Mass. Hospital Association

Nancy Ridley	Director, Division of Food and Drugs Department of Public Health
James McGrath	Division of Food and Drugs Department of Public Health
Vivian Friedman	Division of Food and Drugs Department of Public Health

Invitees not in attendance

Organization
Board of Registration in Nursing
Mass. Veterinary Medicine Association
Mass. Podiatry Society
Mass. State Pharmaceutical Association
Board of Veterinary Medicine
Board of Registration in Podiatry

Massachusetts Policy Group February 8, 1984

Participant	Organization
Patty O'Day	Department of Public Welfare
Carmen Picknally	Assistant Attorney General
Dr. Carl Rosow	Mass. Medical Society
Jim Rooney	Division of Drug Rehabilitation Department of Public Health
Dennis Johnson	Drug Enforcement Administration
Al Russell	Drug Enforcement Administration
Lt. Bill Sutherland	Mass. State Police
Bill Brown	Mass. State Police
Jan Selwitz	Board of Dental Examiners
Mary Regan	Mass. Nurses Association
Marion Metcalf	Board of Registration in Nursing
Howard Saxner	Legal Office Department of Public Health
Barry Rhodes	Applied Resources Corp.
James McGrath	Division of Food and Drugs Department of Public Health
Vivian Friedman	Division of Food and Drugs Department of Public Health
Jerry Janousek	Massachusetts Hospital Association

Invitees not in Attendance

Organization
Board of Registration in Medicine
Board of Registration in Pharmacy
Mass. State Pharmaceutical Association
Mass. Dental Society

EXHIBIT A:

PER CAPITA RANKING
(ARCOS)
MASSACHUSETTS

The source of the data is the Automation of Reports and Consolidated Orders System (ARCOS) from the Drug Enforcement Administration (DEA). The change column represents the difference between 1981 and 1982.

This chart compares the Per Capita distribution of ARCOS reportable drugs.

A value of 1 represents the highest possible per capita consumption. 53 represents the lowest.

DRUGS	1981	1982	CHANGE**
1121 Amphetamine	13	7	-6
1280 Methamphetamine	31	29	-2
1631 Phenmetrazine	37	34	-3
1724 Methylphenidate	45	43	-2
2125 Amobarbital	4	4	0
2270 Pentobarbital	28	28	0
2315 Secobarbital	17	21	+4
2565 Methaqualone	35	36	+1
9041 Cocaine	25	22	-3
9062 Codeine	46	48	+2
9120 Dihydrocodeine	40	42	+2
9130 Dihydrocodeinone	30	40	+10
9143 Oxycodone	2	2	0
9150 Dihydromorphinone	8	8	0
9230 Meperidine	23	25	+2
9250 Methadone	8	8	0
9300 Morphine	15	13	-2
9630 Opium Tincture	14	9	-5
9639 Opium Powdered	47	44	-3
9648 Mixed Alkaloids of Opium	2	2	0

**A negative change value means a relatively higher per capita distribution compared to other states.

Prepared By: Applied Resources Corporation

EXHIBIT B:

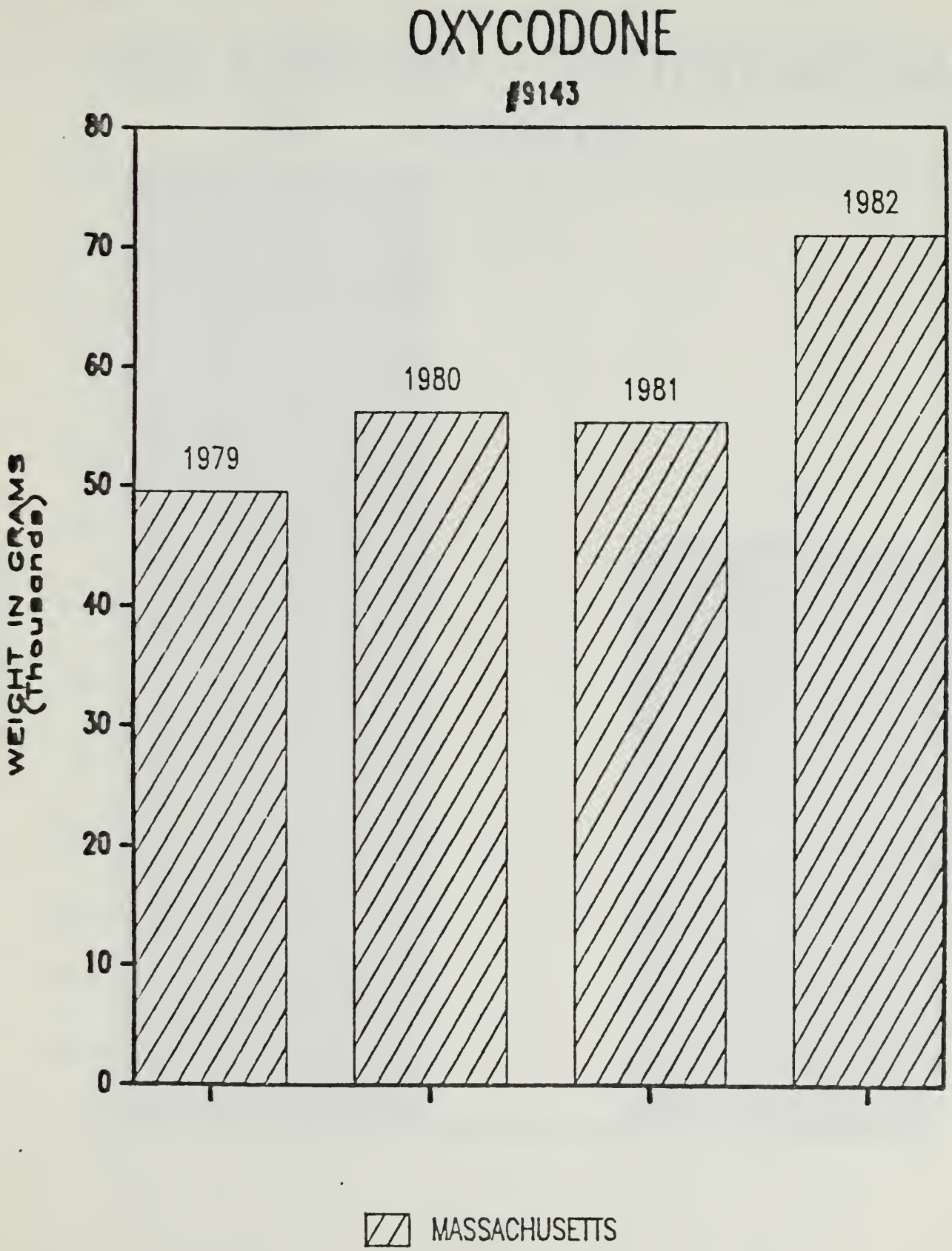
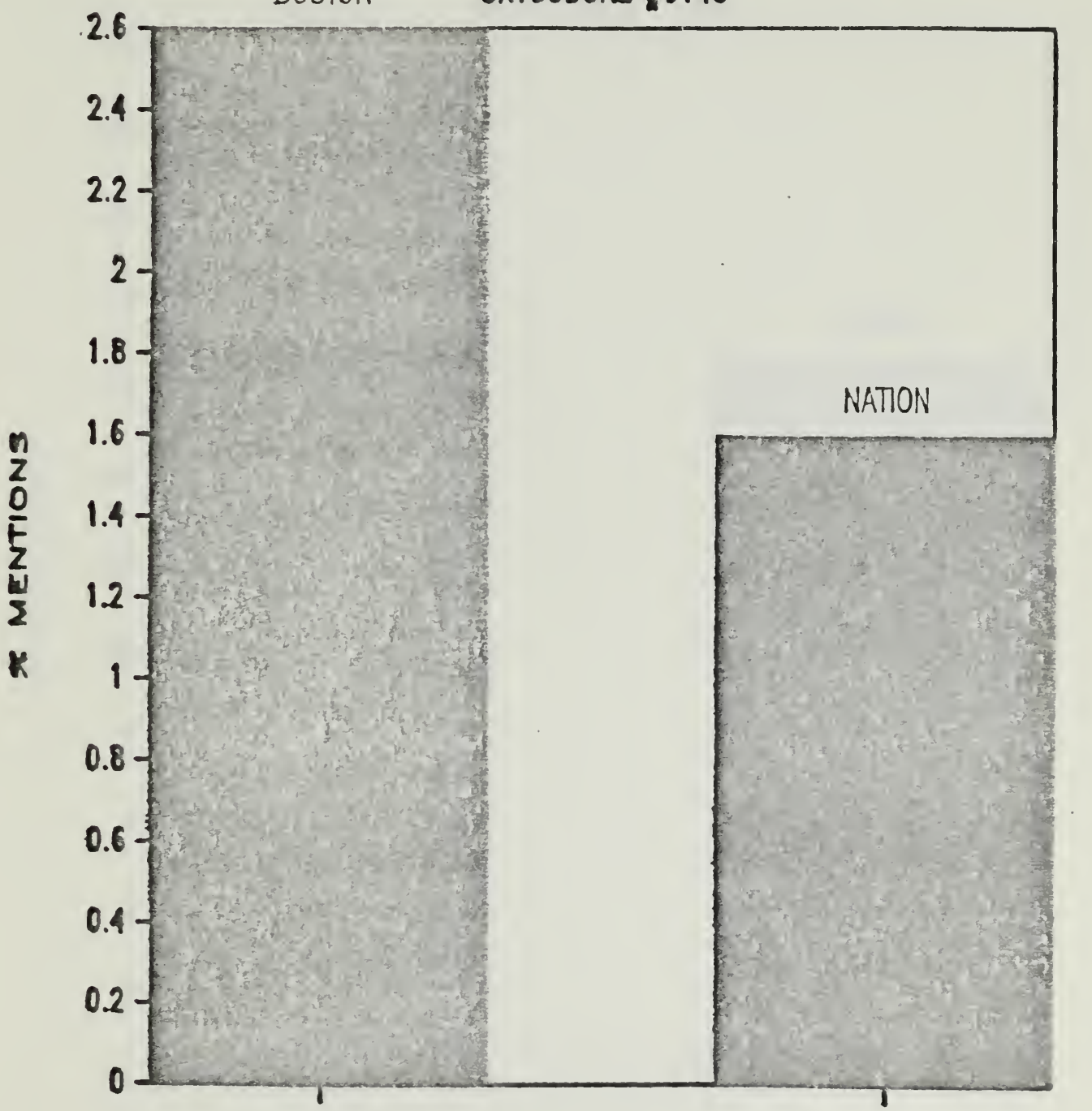

OXYCODONE
#9143
80
70
60
50
40
30
20
10
0
WEIGHT IN GRAMS (Thousands)
1979
1980
1981
1982
MASSACHUSETTS

EXHIBIT C:

1982 DAWN DATA : BOSTON/NATIONAL



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1982 DAWN DATA : BOSTON/NATIONAL

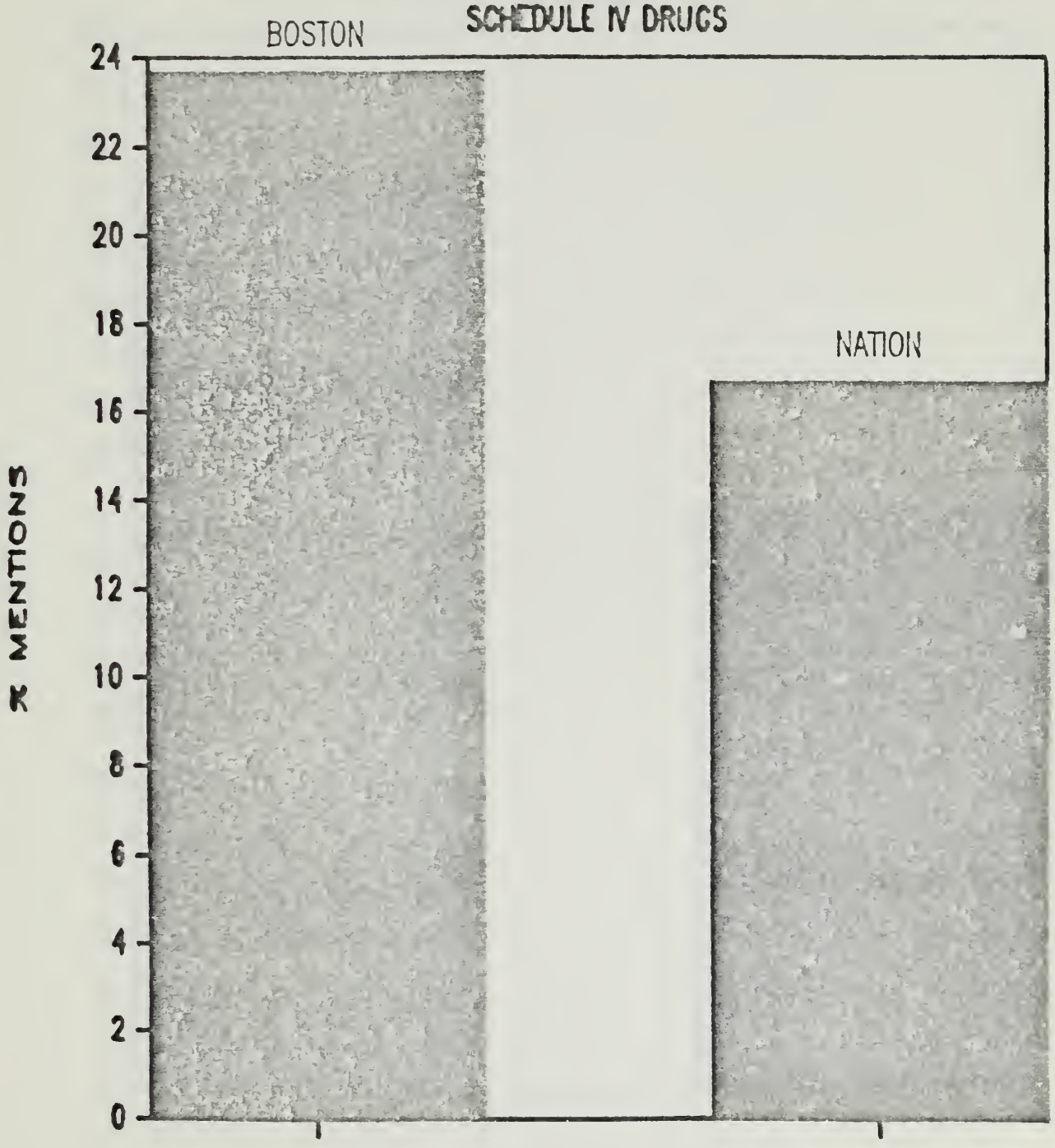


EXHIBIT E:

1982 DAWN DATA : BOSTON/NATIONAL

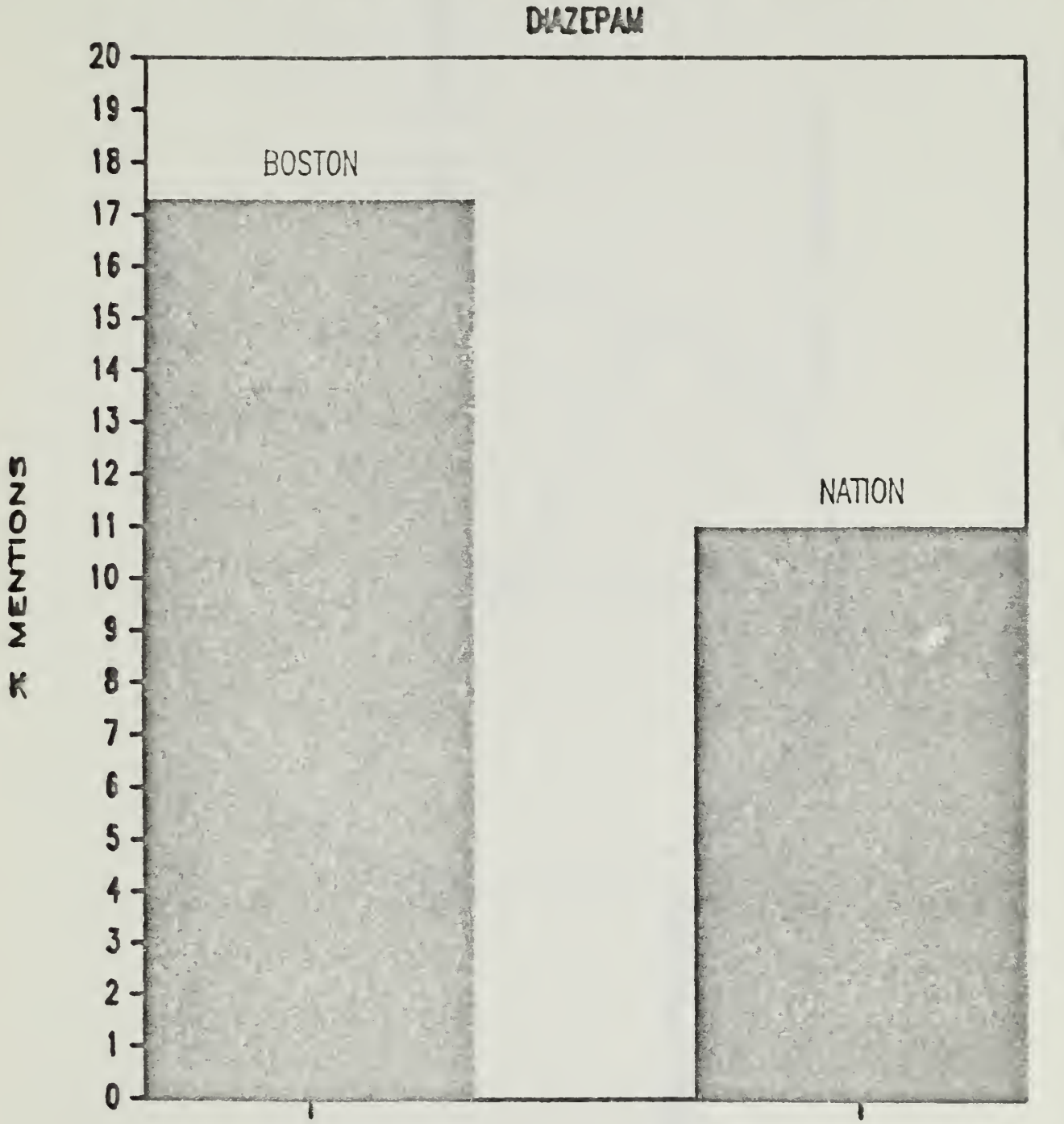


EXHIBIT F:

MASSACHUSETTS LAB SUBMISSIONS

OF PRESCRIPTION DRUGS

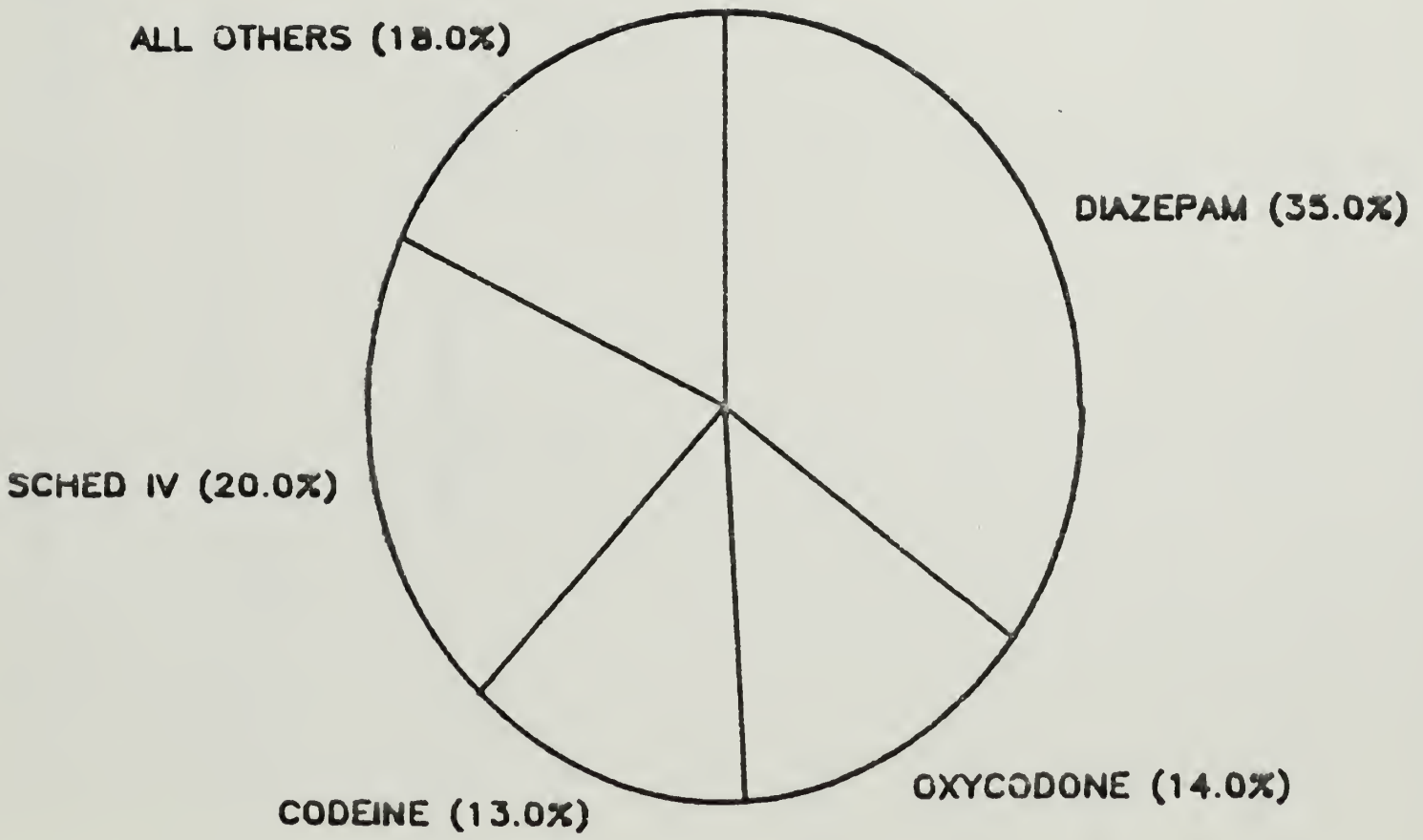


EXHIBIT 6:

CODAP DATA 1981

COMPARISON BETWEEN MASSACHUSETTS AND THE NATION

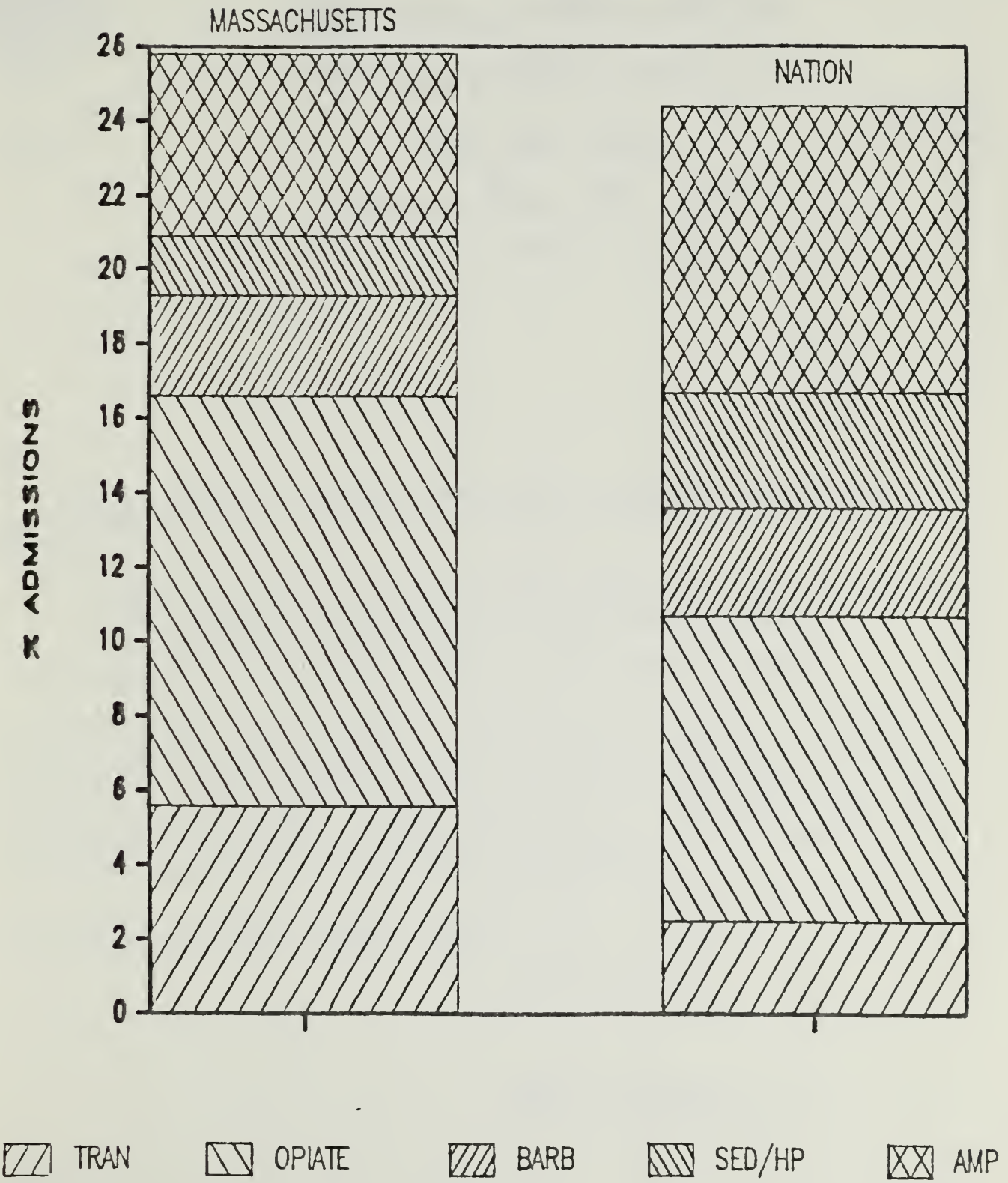
Percent distribution of clients admitted by primary drug of abuse at admission.

PRIMARY DRUG	MASSACHUSETTS	NATION	VARIANCE
Tranquilizers	5.6	2.5	+3.1
Other Opiates	11.0	8.2	+2.8
Barbiturates	2.7	2.9	-0.2
Other Sedatives or Hypnotics	1.6	3.1	-1.5
Amphetamines	4.9	7.7	-2.8
*Total Pharmaceuticals	25.8	24.4	+1.4

*Does not compensate for "look-alike" or other counterfeit pharmaceutical products.

EXHIBIT H:

CODAP DATA 1981



Executive Office of Human Services
Department of Public Health
Division of Food and Drugs
305 South Street
Jamaica Plain, Mass. 02130

Telephone
(617) 727-2670

Ballus Walker Jr. Ph D. M P H
COMMISSIONER

December 14, 1983

Dear :

As you recall, at our last PADS technical group meeting we asked two basic questions of each of your organizations. These two questions are as follows:

1. What three major problems does your organization see as preventing more effective intervention in the drug diversion problem?

2. What three actions can be taken to resolve these problems?

Additionally, the representative from the Medical Society was asked to briefly explain the structure of the Society's program for impaired practitioners, and its success to date. I think as an additional policy issue it would be helpful to have an approximate number of practitioners who have requested to participate in such a program, so that we may share this information with all of our members. In the future, we will request similar information from the other professional organizations.

I appreciate your cooperation on this matter and ask that I receive your responses no later than January 4, 1984.

Sincerely yours,

James A. McGrath
Senior Systems Analyst

JAM/dld

EXHIBIT J:

The Commonwealth of Massachusetts

Department of Civil Service and Registration

Board of Registration in Pharmacy

Leverett Saltonstall Building, Government Center

100 Cambridge Street, Boston 02202

January 31, 1984

James A. McGrath, Senior Systems Analyst
Department of Public Health
Division of Food and Drugs
305 South Street
Jamaica Plain, Massachusetts 02130

Dear Jim:

In response to your correspondence of December 14, 1983, three major problems in the drug diversion are as follows:

1. Lack of inspections where drugs are handled.
2. Overlapping of the authority of regulatory agencies.
3. Regulatory agencies lack of communication and working together.

The Board of Registration in Pharmacy, by statute, is supposed to have six (6) agents but presently only has three (3). We have 1350 Retail Pharmacies, about 200 Wholesale Drug Licensees and 7,000 Registered Pharmacists. Our agents are now pooled in the Investigative Unit acting on complaints and routine inspections are not encouraged.

As you know, education and consequences of violations of the laws are a major factor in promoting Voluntary Compliance.

In most states the Board of Registration in Pharmacy regulates wherever drugs are dispensed and handled. In Massachusetts, the Board shares much of the authority with the Department of Public Health. The Dept. of Public Health has authority over Hospital and Clinic Pharmacies. The Dept. of Public Health Rules and Regulations in these matters are about twelve years old. The D.P.H. has only two (2) inspectors, one of which is not a Registered Pharmacist. Many Hospital Pharmacies have never seen an inspector since they opened. With the advent of Clinics and HMO Health Plans more prescriptions are now going out into the community. These prescriptions are subject to the same rules and regulations and laws as does the community pharmacy prescriptions.

The DIU of the state police was funded and active from 1974 to 1978. It was inactive from 1978 to 1984. It has now been refunded and is active again. This was a six (6) year lapse. There are now only three Board Agents. The DEA covers all New England with two agents. Since all of these agencies are short-handed and understaffed, if they could work in conjunction with each other, I believe this could be more effective.

Sincerely,

EXHIBIT J:

MASSACHUSETTS GENERAL HOSPITAL ◆ HARVARD MEDICAL SCHOOL

ASSISTANT ANESTHETIST
DEPARTMENT OF ANESTHESIA
Massachusetts General Hospital
Boston, Massachusetts 02114
(617) 726-8812

CARL E. ROSOW, M.D.
Assistant Professor of Anaesthesia

18 January 1984

James A. McGrath
Senior Systems Analyst
Massachusetts Department of Public Health
Division of Food and Drugs
305 South Street
Jamaica Plain, Massachusetts 02130

Dear Jim:

As spokesman for the Massachusetts Medical Society I would like to respond to the questions raised in your 14 December 1983 letter to Neil Foley.

There are several major obstacles to effective control of prescription drug abuse:

1. Lack of recognition of the problem by both practitioners and consumers seems to be the rule. Those physicians who are aware of drug diversion and overprescribing in the abstract may still have difficulty recognizing it in specific clinical situations.

   The obvious remedy is education for both consumers and professionals. The most cost effective means for physician education is probably through one or more concise pamphlets on the subject. The Society will shortly issue one such pamphlet dealing with the fundamental laws and regulations governing prescribers in the Commonwealth.

2. Substantial difference of opinion will probably always exist as to what constitutes "abusive" prescribing. For example, the limits of legitimate drug therapy for pain or psychiatric illness may depend tremendously on patient and physician variables as

(continued)

well as the abuse liability of the drug being prescribed. Furthermore, drug indications and doses (and physician preferences) are not static but change over time.

There are no easy solutions to this problem. Regulations cannot be expected to provide more than general guidelines for prescribers, and each case must ultimately be judged individually -- and according to prevailing standards of medical practice.

3. There is a lack of patient-specific and physician-specific information on the scope and severity of the drug diversion problem. We have all discussed at length the limitations of available drug abuse data (e.g., DAWN, ARCOS, MMIS, Police Records, etc.).

In 1982, after some hesitation, the Society took the position that a duplicate prescription program was likely to be an effective way to address this problem. We continue to support the institution of such a program in Massachusetts, subject to the provisos outlined in our letter to Representative Aleixo (copy enclosed). We are hopeful that information generated from PADS will be helpful in justifying such a program.

Yours truly,

Carl E. Rosow, M.D., Ph.D.
Chairman
Committee on Drugs and Therapeutics
Massachusetts Medical Society

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Enclosure

MASSACHUSETTS MEDICAL SOCIETY
22 The Fenway, Boston, Massachusetts 02215 (617) 536-8812 WATS 1-800-952-7418

April 26, 1982

The Honorable Theodore J. Aleixo, Jr.
House Chairman - Health Care Committee
State House - Room 130
Boston, MA 02133

Dear Representative Aleixo:

This letter is in response to two bills recently filed which address the problem of prescription drug abuse in Massachusetts. They are Senate Bill No. 508 - RESOLVE: PROVIDING FOR AN INVESTIGATION AND STUDY BY A SPECIAL COMMISSION RELATIVE TO THE CONTROL OF FRAUDULENT PRESCRIPTIONS, and House Bill No. 5867 - AN ACT PROVIDING FOR ADDITIONAL RECORD KEEPING PERTAINING TO THE DISPENSING OF CONTROLLED SUBSTANCES.

After initial review by the Massachusetts Medical Society, these bills were referred to the Society's Committee on Drugs and Therapeutics for evaluation and a recommendation on what position the Society should take on them. At its meeting of April 15, 1982, the Committee voted unanimously to endorse the concept of a multiple prescription program to help address the problem of prescription drug abuse in the Commonwealth.

The Committee, however, has some serious concerns about instituting such a program as it was outlined in House Bill No. 5867 and would like to offer the following recommendations:

1) That provision be made in the bill to guarantee patient and physician confidentiality and that the administrative agency be the Department of Public Health, not the State Police.

2) That physicians and pharmacists must actively participate on the body that will control the collection and use of the data gathered and generated by a computer program.

3) That this data must be used for educating physicians and patients.

4) That information on federal controlled substance tracking and other states' multiple prescription programs be evaluated before finalizing such a program in Massachusetts.

5) That there be an adequate appropriation to a special unit established within the Department of Public Health to administer and enforce the program in Massachusetts.

We would be pleased to work with the Joint Legislative Committee on Health Care or any study commissioned for this purpose in order to ensure the

Exhibit J

EXHIBIT J:

MNA Massachusetts Nurses Association

March 21, 1984

James A. McGrath
Senior Systems Analyst
Mass Department of Public Health
Division of Food and Drugs
305 South Street
Jamaica Plain, MA 02130

Dear Jim:

The Department of Nursing at the Massachusetts Nurses Association feels the major obstacles to having effective control of prescription drug abuse are:

1. Lack of knowledge and understanding about the drug abuse problem.
2. Differences in opinions about what constitutes abuse vs. use.
3. Lack of knowledge about how to handle drug abusers when identified.

Yours truly,

Mary H. Regan

Mary H. Regan, R.N., M.S.
Director, Department of Nursing

MHR/mu

development of a legislative solution to the problem of prescription abuse in the Commonwealth. The Society has already begun obtaining information on other states' multiple prescription programs and we would be happy to make such materials available.

Sincerely,

Stanley M. Wyman, M.D.
President

Bartley G. Cilento, M.D.
Chairman
Committee on Legislation

Carl E. Rosow, M.D.
Chairman
Committee on Drugs and
Therapeutics

SMW/BGC/lej